

Aliphatic Esters Category - Comments of Environmental Defense

(Submitted via Internet)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Aliphatic Esters Category.

The test plan for the aliphatic esters category was prepared by the American Chemistry Council's Aliphatic Esters Panel, which represents 19 member companies. The test plan encompasses 45 HPV aliphatic esters used in a variety of applications, including lubricants, plasticizers, emollients, solvents and cosmetic ingredients. Thus, there is ample opportunity for human exposure.

This is a complicated test plan but in general it is well written and objective in its description of the available data. The sponsor divides the 45 chemicals into 5 subgroups based on physiochemical properties and structural characteristics. Establishment of the 5 subgroups is justified and provides a reasonable framework for evaluating the adequacy of existing data and for using a read-across approach for the fulfillment of HPV requirements.

Although we agree with the sponsor that the aliphatic esters, for the most part, possess low mammalian and ecological toxicity, we do have a few concerns. One concern is that there are no reproductive or developmental studies for subgroup D (sorbitan analogs) and the sponsor recommends that a technical discussion be used in lieu of data to fulfill requirements for these endpoints. In our view, the justification for foregoing a reproductive/developmental study for the seven chemicals in subgroup D is inadequate. The fact that sorbitol is not a reproductive toxicant certainly does not provide a convincing argument that the more complex sorbitan analogs covered here have no reproductive toxicity. Accordingly, we recommend that a combined reproductive/developmental study be conducted on sorbitan monostearate or another prototypical representative of subgroup D.

We have a similar concern for subgroup E, for which only one reproductive/developmental study was conducted but the report of the study is apparently unavailable. Inasmuch as subgroup E is comprised of 19 chemicals, we do not find the sponsor's justification sufficient to obviate the need for reproductive and developmental toxicity data. Therefore, we recommend that at least one prototypical member of this group be tested for reproductive and developmental toxicity.

Thank you for this opportunity to comment.

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